REMARKS/ARGUMENTS

The Examiner's continued attention to the present application is noted with appreciation.

Claims Amendment. Applicant has amended claims 7, 10, 17, 18, and 19. Claim 9 is canceled. New claim 22 is added. The claims at issue are claims 7, 10, 17, 18 and 22; the remaining claims are canceled or withdrawn. Support for new claim 22 is found at, inter alia, page 1, lines 18-24; claims 1 - 3 as filed and Figs. 1 and 3.

35 U.S.C. § 102 Rejection as to Levine et al. Claims 7, 9, 10, 17 and 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Levine et al. Applicant respectfully traverses this rejection.

Claim 7 is amended such that it relates to a "method of treatment of a patient with an RNA virus", and further by addition of a wherein clause providing "wherein the RNA virus replication rate is reduced." It is submitted that with the amendment to claim 7, this claim is allowable over Levine et al. Similarly, new claim 22 is drawn to "a method of reducing the viral replication rate of HIV virus," and it is submitted that this claim is similarly allowable over Levine et al.

With respect to Levine et al., this reference is related only to treatment of HIV-related lymphoma by administration of bleomycin. The most recent Office Action asserts that "a condition that arises commonly as a result of a virus infection, but rarely in its absence, may be understood to have been caused by that virus." However, Levine et al. states as follows:

> HIV, per se, has not been detected within the genome of AIDS-related B-lymphoma cells, and is not considered the direct etiology of this tumor. However, HIV may be operative indirectly by inducing chronic B cell activation and proliferation in the setting of underlying immunosuppression.

Levine et al. at page 524, first column, first full paragraph (emphasis added). That is, the body of a patient with AIDS is, as a result of a suppressed immune system, less capable of fending off both exogenous (i.e., bacterial or viral infections) and endogenous (i.e., cancer) diseases. One complication that AIDS patients may suffer from, in a relatively late stage of HIV manifestation (*see* Levine et al., pages 517, last three lines) is lymphoma, a type of cancer. It is known that various types of cancer may be treated with bleomycin. In this regard, Levine is simply utilizing a known chemotherapy agent, bleomycin, to treat a

cancer. However, Levine et al. specifically teaches away from the lymphoma being "caused by an RNA virus" (in the words of claim 17), because Levine et al. states that the RNA virus, here specifically the HIV, "is not considered the direct etiology of this tumor." Merely because lymphoma may be "related" to or more prevalent in HIV infection (i.e., it is "operative indirectly") does not imply causation. Obviously lymphoma occurs in individuals who do not have HIV infection. Levine et al. does not anticipate because it does not teach or suggest using bleomycin to treat a "disease caused by an RNA virus", but merely and conventionally using bleomycin to treat lymphoma in patients who also have HIV infection. That the incidence of lymphoma may be higher in AIDS patients than in the general population (though Levine et al. teaches that lymphoma is present in only about 3% of newly diagnosed cases of HIV infection, *see* page 517, last three lines) does not imply that HIV infection is "causative", particularly given the explicit statement of Levine et al. that it is, at most, only possibly (i.e., Levine et al. states "may be") related ("operatively induced") to a suppressed immune system, which suppressed immune system itself results from HIV. Lymphoma may, however, also develop in patients with immunodeficiency induced by other means, such as induced by immune suppressive therapy.

With respect to claim 7, as amended the claim is drawn to "treatment of a patient with an RNA virus", and further "wherein the RNA virus replication rate is reduced." There is no teaching or suggestion in Levine et al. that bleomycin may be used in treatment of an RNA virus, or that it will result in reduction of the viral replication rate. See, e.g., Levine et al. at page 518, second full paragraph, and 519, first full paragraph, describing that all patients received ddC (zalcitabine) specifically to control the underlying HIV infection.

With respect to new claim 22, this is drawn to a method of "reducing the viral replication rate of HIV." There is no suggestion or teaching in Levine et al. that anticipates this claim.

35 U.S.C. § 102 Rejection as to Cheng et al. Claims 7, 17 and 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cheng et al. Applicant respectfully traverses this rejection.

Claim 7 is amended so that it is drawn to an "RNA virus." Claims 17 and 18 are drawn to a "disease caused by an RNA virus," and in the case of claim 18, specifically to HIV. Cheng et al. discloses

only that bleomycin is known for "treatment of Condyloma acuminate caused by human papilloma virus..." U.S. Patent 5,795,911, col. 1, lines 34-44. However, human papilloma virus (HPV) is a DNA virus. Attached hereto are pages 1291-1292 from PDR Medical Dictionary, First Edition (Medical Economics, Montvale, NJ, 1995), which defines "papilloma virus" as a "genus of viruses... containing DNA" and which are "differentiated by DNA homology." Because Cheng et al. only discloses that bleomycin may be used for treatment of a condition caused by a specified DNA virus, it does not anticipate as to claims drawn to use in treatment of an RNA virus or disease caused by an RNA virus, including HIV.

Newly Cited References: Disclosed herewith are two new references, Ohta et al. and Gompels et al.

Gompels et al. is substantively identical to Levine et al. It simply discloses a method of treatment of Kaposi sarcoma. This is comparable to Levine et al, who treat AIDS-related lymphoma by using a chemotherapeutic cocktail (M-BACOD) including bleomycin, and additionally the virus inhibiting agent Zalcitabine. Both papers do not use bleomycin as an agent to destroy a virus. Kaposi sarcoma and lymphoma are not limited to HIV infected patients and therefore cannot be regarded as the characteristic symptom or as the symptom to which the disease is limited. They are one out of a number of consequences of an affected immune system, in case of AIDS caused by HIV. No relation or suggestion is made in these papers for the application of bleomycin in the treatment of AIDS by killing the HIV virus by bleomycin.

Regarding Gompels et al. it is known that: "Kaposi sarcoma is not directly induced by HIV. For example, iatrogenic Kaposi sarcoma may develop receiving immuno suppressive therapy. Epidemic Kaposi sarcoma appears approximately in 21% of homosexual men with AIDS. The etiologic agent appears to be human herpes-virus-8 (HV-8) (DeVita, V.T., Hellman, S., Rosenberg, S.A., *Cancer, Principles and Practice of Oncology*, 6th edition, Lippincott Williams and Wilkins eds., p1997, see attached copy).

With respect to Ohta et al., this discloses a method to kill tumor cells (HeLa celline) by a new compound called KM043, which inhibits a.o. DNA polymerases (including HIV-RT). Ohta et al. does not describe the use as an effect on the KM-43 treatment in killing HeLa cells. Bleomycin is only mentioned as

a known agent against cancer, by destroying the (DNA of the) cancer cell. Ohta et al. did not look to the effect of bleomycin on HIV-RT activity. Ohta et al. did not look to an application of bleomycin in the treatment of AIDS/HIV and did not disclose any possible relationship. Ohta et al. further did not look to any effect of bleomycin on the RNA or DNA of HIV or any other virus.

Conclusion. In view of the above amendments and remarks, it is respectfully submitted that all grounds of rejection and objection have been avoided and/or traversed. It is believed that the case is now in condition for allowance and same is respectfully requested.

If any issues remain, or if the Examiner believes that prosecution of this application might be expedited by discussion of the issues, the Examiner is cordially invited to telephone the undersigned attorney for Applicant at the telephone number listed below.

Also being filed herewith is a Petition for Extension of Time to November 22, 2004, with the appropriate fee. Authorization is given to charge payment of any additional fees required, or credit any overpayment, to Deposit Acct. 13-4213. A duplicate of this paper is enclosed for accounting purposes.

Respectfully submitted,

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